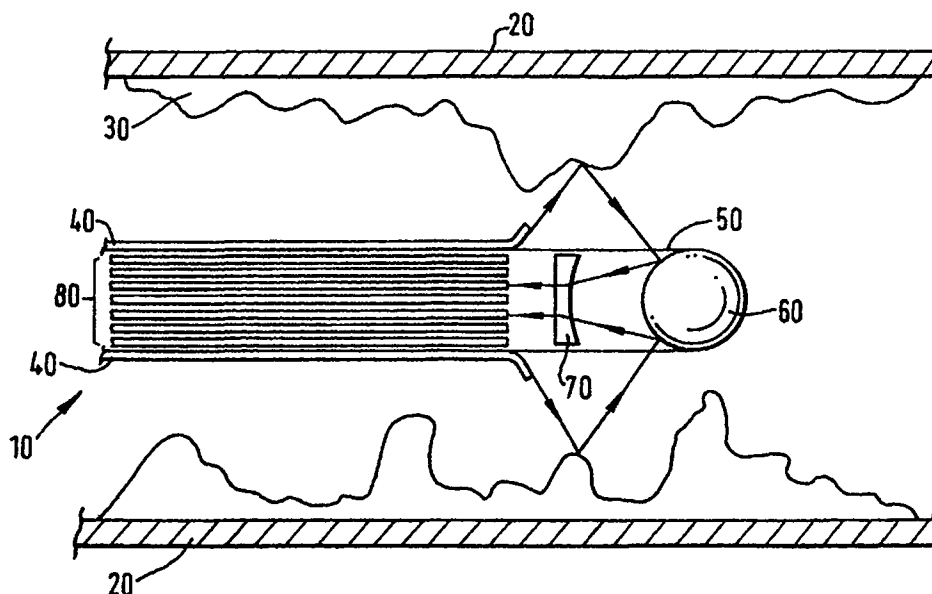


## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/GB98/01045 (22) International Filing Date: 9 April 1998 (09.04.98) (30) Priority Data: 9707414.0                      11 April 1997 (11.04.97)                      GB (71) Applicant (for all designated States except US): IMPE- RIAL COLLEGE OF SCIENCE, TECHNOLOGY AND MEDICINE [GB/GB]; Exhibition Road, London SW7 2AZ (GB). (72) Inventors; and (75) Inventors/Applicants (for US only): KITNEY, Richard, Ian [GB/GB]; Imperial College of Science, Technology and Medicine, Centre for Biological and Medical Systems, Exhibition Road, London SW7 2BX (GB). DOWDY, Cliff [US/US]; 14000 North Frisco Road, Piedmont, OK 73078 (US). (74) Agents: MAGGS, Michael, Norman et al.; Kilburn & Strode, 20 Red Lion Street, London WC1R 4PJ (GB).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).  <b>Published</b> With international search report.	

(54) Title: ANATOMICAL PROBE



## (57) Abstract

A probe (10) for examining body parts has a first fibre optic wire (40) which can illuminate the walls of a blood vessel (20) or internal organ, for example, with infrared light. The light is reflected from the walls and collected by a lens system which contains a reflective ball (60) and a collimating lens (70). The light then enters a plurality of fibre optic detector wires (80) situated within the first, illuminating fibre optic wire (40). This signal is fed first to a frequency shifter (150) to generate visible light and then to a monitor (160) which allows real time imaging of the walls of the blood vessel (20). The probe provides high resolution imaging coupled with a small diameter. For diseased blood vessels, therefore, it is thus possible to deploy the probe together with a standard 1 millimetre diameter balloon catheter (200) to permit detection and treatment of arterial disease substantially simultaneously.

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### Anatomical Probe

This invention relates to a probe for anatomical parts, and particularly, but not exclusively, to a probe for use in the detection and treatment of diseases in internal organs and blood vessels, particularly arteries.

5

Probes have been developed for investigating a wide range of internal body parts. For example, in recent years, angioplasty has been developed as a technique for the treatment of atherosclerosis, or narrowing of blood vessels in arteries, caused by the build up of cholesterol and the like. The technique is particularly employed to remove plaque from the main arteries around the human heart.

In one method, a guide wire is threaded through an artery, typically in the groin area, and up to the region of the heart. A first catheter, having a fluoroscope on one end, is then passed over the guide wire in the artery until the fluoroscope is located in the vicinity of any potentially constricted areas. The fluoroscope then generates a source of low energy X-rays, which are reflected from the arterial walls and detected. The detected X-rays are used to construct a picture of the interior of the artery to pinpoint particular areas of plaque build up.

Following the mapping of the area of interest, the first catheter with the fluoroscope attached is removed from the artery entirely. A second catheter, known as a balloon catheter, is then threaded onto the guide wire and up into the area of the blood vessel which has previously been mapped by fluoroscopy. The balloon catheter has an expandable elastic bladder towards the end of the catheter that enters the area of interest; preferably this bladder is in turn surrounded by a wire mesh.

Using the fluoroscopic mapping as a guide, the bladder of the balloon catheter is slid into a position of high plaque build up. The bladder is then expanded which crushes the plaque.

5

There are a number of problems with this approach. Firstly, two separate catheters are required to be inserted into the patient, which is time consuming for the medical personnel involved and also causes discomfort in the patient. Further, the resolution which is obtainable using the low energy X-rays is  
10 generally poor, and it is difficult to pinpoint with any accuracy those areas of the arteries which are to be treated. To address this problem, ultrasound transducers have been employed on the catheter instead, in order to produce an ultrasonic image of the arterial cross-section. However, the resolution they provide is still poor.

15

One technique for improving the resolution would be to increase the energy of the X-rays by increasing the size of the crystal. However, this would require a new, larger diameter catheter which in turn would require approval by the relevant health authority (for example, the F.D.A. in the United States) which  
20 can take many years.

Yet another disadvantage of the prior art arrangement is that, even with accurate imaging of the arteries by the fluoroscope, it is difficult to know with certainty that the subsequently inserted balloon catheter is in precisely the  
25 desired location previously determined by the fluoroscope.

Similar probes for other body parts are known, such as gastroscopes for investigating the stomach and so forth. These probes also typically employ X-ray or ultrasonic imaging techniques and therefore suffer from the above-

mentioned resolution problems.

It is an object of the present invention to at least alleviate these problems with the prior art.

5

According to the present invention, there is provided a probe for examining the walls of anatomical parts (particularly cardiac arteries), comprising an illuminator arranged to illuminate the walls of the anatomical part with electromagnetic radiation, and a lens system for receiving electromagnetic  
10 radiation reflected from the walls of the anatomical part.

Using an illuminator and a lens system allows an image of the walls to be generated which is far superior to that generated by prior art probes of a similar diameter that use ultrasound or X-ray transducers.

15

Preferably, the probe also comprises imaging means for receiving the reflected electromagnetic radiation from the lens system. This may be one or more fibre optic wires, for example.

20 Additionally or alternatively, the illuminator may be a fibre optic illuminator, such as a fibre optic wire. If the imaging means is also a fibre optic wire, it may preferably be located within the fibre optic illuminator. Thus, a probe with a similar diameter to those of the prior art is provided, but with substantially better resolution.

25

Preferably, the lens system comprises a convex reflector for guiding the electromagnetic radiation reflected from the body part walls back towards the end of the fibre optic illuminator, and a lens arranged to collimate the

electromagnetic radiation from the convex reflector.

The radiation reflected from the walls of the anatomical part tends to arrive back at the probe at an obtuse angle relative to the fibre optic illuminator. A  
5 convex reflector and collimating lens are therefore preferable to deflect that reflected light such that it is made generally parallel to the illuminator once more.

The convex reflector may conveniently be a reflective ball, which may be  
10 attached to the fibre optic illuminator by a sheath substantially transparent to the electromagnetic radiation reflected from the walls of the anatomical part. For example, the ball may be formed of stainless steel.

Preferably, the probe is adapted to examine blood vessel walls. Alternatively,  
15 the probe may be adapted to examine internal organs such as, for example, the stomach. It may be positioned within the organ or blood vessel by means of a conventional catheter.

The invention also preferably extends to a system for operating the probe of  
20 the present invention. The system comprises generator means for generating electromagnetic radiation, the illuminator being arranged to receive the electromagnetic radiation from the generator means; and display means for receiving the reflected electromagnetic radiation from the imaging means and displaying an image of the wall of the anatomical part.

25

Blood is largely opaque to visible light, and it is therefore preferable that the generator means is arranged to generate electromagnetic radiation in the infrared region of the electromagnetic spectrum particularly if the probe is

adapted to examine blood vessel walls. The system may further comprise a frequency shifter arranged to receive the reflected infrared radiation from the fibre imaging means and shift the frequency thereof into the visible part of the electromagnetic spectrum prior to the radiation being received by the display  
5 means.

The probe, when adapted to examine blood vessel walls, may find particular application in combination with a catheter, and especially a balloon catheter which permits the removal of plaque formed on the blood vessel walls. The  
10 probe of the present invention provides relatively high quality images, yet is of a small enough diameter to be inserted into a 1 millimetre diameter balloon catheter. As such, it is possible to generate images of the blood vessel walls with the probe, and substantially simultaneously remove the plaque therefrom with the balloon catheter. As the balloon catheter has already been approved  
15 by the relevant health and safety commissions, approval would only need to be sought for the probe part of the combination.

It is preferable to include a cage around the balloon of the balloon catheter to assist further in the removal of the plaque.

20

The present invention can be put into practice in various ways which will now be described by way of example with reference to the accompanying drawings in which:-

25 Figure 1 is a sectional view of a probe according to a preferred embodiment of the present invention;

Figure 2a and 2b are sectional views of a detachable handle for the probe of

Figure 1.

Figure 3 shows a system for implementing the probe of Figures 1 and 2;

5 Figure 4 is a section of a diseased blood vessel; and

Figures 5a - 5e are schematic images obtained using the probe of the present invention when at the locations AA', BB', CC' DD' and EE' respectively.

10 Figure 1 shows, in section, the end of a probe, generally designated 10, located within the walls of a blood vessel 20 having arteriosclerosis or plaque build-up 30.

The probe 10 consists of a fibre optic illuminator wire 40 of approximate  
15 diameter 380 micrometers. In this illustrative embodiment, the probe is being used to investigate arteriosclerosis in the region of the human heart and is inserted through a blood vessel in the groin. Thus, the fibre optic illuminator wire 40 is typically a metre or more in length, and only the distal end which is used to examine the diseased area is shown in Fig. 1.

20

Attached to the distal end of the fibre optic illuminator wire 40 (i.e. the end which is inserted into the blood vessel) is a sheath 50 which is optically transparent, particularly in the infrared region of the electromagnetic spectrum.

A first end of the sheath 50 is bonded or otherwise attached to the inner  
25 diameter of the fibre optic illuminator wire 40, the other end of the sheath 50 being attached to a reflective ball 60. The ball in this embodiment is formed of stainless steel and is approximately 350 micrometers in diameter, although any suitably reflective material could be used instead of stainless steel.



A lens 70 is located within the sheath 50 between the ball 60 and the distal end of the fibre optic illuminator wire 40. This lens is a collimating lens, such as a plano-concave or doubly concave lens, whose purpose will be described in  
5 more detail below.

Finally, a plurality of fibre optic detector wires 80, each having a diameter substantially smaller than the diameter of the fibre optic illuminator wire 40, are located within the fibre optic illuminator wire 40.

10

As shown in Figures 2a and 2b the probe has a removable handle 90 attached to the proximal end of the probe (i.e. the end not inserted into the blood vessel). The handle 90 assists in inserting the probe 10 into the blood vessel. In Figure 2a, the handle is shown attached to the proximal end of the probe 10  
15 and is secured in place by a collet ring 100. In this attached position, the fibre optic illuminator wire 40 is illuminated by a source of infrared radiation, as shown in Figure 3 and explained in more detail below. The light from the source of infrared radiation is coupled to the fibre optic illuminator wire 40 via an annular ring 110, the cable from the source of infrared radiation being  
20 anchored into the handle 90 by a cable gland 120 or the like.

When the probe is attached to the handle 90 (Figure 2a), the fibre optic detector wires 80 abut an optical detector system shown schematically as reference numeral 130. The output of this detector system 130 is connected to  
25 a frequency shifter and a monitor as described below in connection with Figure 3.

The manner in which plaque build-up 30 on the blood vessel walls 20 is

detected will now be described by reference to Fig. 3. A source of infrared radiation 140, such as a variable-frequency carbon dioxide gas laser, is connected to the fibre optic illuminator wire 40. The probe 10 is then inserted into a suitable blood vessel and slowly pushed up that blood vessel, with the assistance of the handle 90 of Figures 2a and 2b, until the distal end of the probe 10 reaches a region of interest. The distal end of the fibre optic illuminator wire 40 is bent so that infrared light emitting from the wire 40 is directed towards the walls of the blood vessel.

10 The light is reflected off the walls of the blood vessel 20 and back through the transparent sheath 50 before striking the ball 60. The ball 60, acts as a spherical mirror and causes the light reflected off it to be directed back towards the end of the fibre optic illuminating wire 40, as shown in Fig. 1. The light also converges upon reflection off the stainless steel ball 60.

15 The collimating lens 70 is located such that the converging light reflected off the ball 60 is collimated into a parallel beam. This parallel beams enters the fibre optic detector wires 80 and passes along these to a frequency shifter 150, which shifts the frequency of the infrared light that has been reflected off the walls of the blood vessel into the visible region of the electromagnetic spectrum. This is preferably done in software, for example using Fourier analysis or a heterodyning technique. Alternatively, it could be done in hardware. The frequency shifter 150 also processes the light and sends an output to a monitor 160 which allows a medical practitioner to view, in real time, the cross section of the blood vessel. Preferably, the source produces spread-spectrum IR radiation or alternatively produces a time-varying frequency. Different aspects of the plaque that has built up within the blood vessel may then be studied at different frequencies.

Figure 4 shows, in detail, a blood vessel 20 having a region of plaque build-up or arteriosclerosis 30. As the distal end of the probe is moved, slowly, along the blood vessel from left to right, the image on the monitor 160 of Figure 2  
5 will change as the depth of plaque on the walls of the blood vessel changes. Schematic representations of typical images that would be seen on the monitor 160 as the probe passes through lines AA', BB', CC', DD' and EE' are shown in Figs. 5(a) to 5(e) respectively.

10 Previously, it had been necessary to insert a guide wire into the blood vessel, slide a first catheter having an ultrasonic or X-ray transducer over the guide wire to map the area of interest, and then remove that first catheter and insert a second, balloon catheter with the guide wire still in place. The probe of the present invention is sufficiently small in diameter, while still giving good  
15 image resolution, that it can itself be used as a guide wire with a 1 millimetre diameter balloon catheter slid around it. The guide wire may be anything between 0.25 mm and 3 mm in diameter. Such an arrangement is shown in Fig.3. The technique for inserting the probe will now be described, referring also to Fig. 2b.

20

The probe is inserted into the blood vessel up to the region of interest. The handle 90 is then removed from the proximal end of the probe 10 by unscrewing the collet ring 100. Because the fibre optic illuminator wire 40 and the fibre optic detector wires 80 are not mechanically coupled to the  
25 handle, as explained above, removal and reattachment of the handle is relatively straightforward. A balloon catheter 200 is then slid over the fibre optic illuminator wire 40 until a balloon 210 is also located within the diseased region of interest. The handle 90 can then be reattached to the probe by

tightening the collet ring 100 once more.

Provided the balloon 210 is then fixed at a given distance behind the probe, the balloon catheter 200 and probe 10 can be pushed slowly in tandem further  
5 along the blood vessel, and as the probe locates regions to be treated, the balloon 210 can be expanded, using a controller 230, to crush the plaque. Alternatively, the probe tip may repeatedly be pulled back in small steps (say 1 mm each), with a full spectral sweep made at each step. Knowing the spring  
between the steps, the plaque may then be reconstructed in 3-dimensions. A  
10 pull-back and probe-tip location device (not shown) may be provided to assist this process. Preferably, the balloon is surrounded by a wire mesh or stent 220 to assist in the crushing of the plaque.

It will be apparent to the skilled person that a number of modifications could  
15 be made to the probe. For example, rather than using a stainless steel ball, any form of convex mirror could be used instead. Further, it may be desirable, rather than bending the end of the fibre optic illuminator wire 40, to locate a prism at that end instead in order to direct the longitudinal light emitted from the illuminator cable towards the walls of the blood vessel.

20

Further, the probe is not restricted to examination of blood vessels. Other body parts, such as internal organs, are equally susceptible to investigation by a probe employing the fibre optic imaging system described in relation to blood vessel probes. For example, a three-dimensional image of the interior  
25 walls of the stomach may be obtained by employing the probe of the present invention as a gastroscope. Alternatively, the probe of the present invention may be used to investigate the airways or the oesophagus of the human or animal patient.

CLAIMS

1. A probe for examining the walls of anatomical parts, comprising an illuminator arranged to illuminate the walls of the anatomical part with  
5 electromagnetic radiation, and a lens system for receiving electromagnetic radiation reflected from the walls of the anatomical part.
2. A probe as claimed in claim 1, further comprising imaging means for receiving the reflected electromagnetic radiation from the lens system.
- 10 3. A probe as claimed in claim 2, in which the imaging means includes at least one fibre optic wire.
4. A probe as claimed in any one of the preceding claims, in which the  
15 illuminator includes a fibre optic illuminator.
5. A probe as claimed in claim 4 when dependent upon claim 3, in which the fibre optic illuminator is a further fibre optic wire.
- 20 6. A probe as claimed in claim 5, in which the imaging means is arranged within the fibre optic illuminator.
7. A probe as claimed in any one of the preceding claims, in which the lens system comprises a convex reflector for guiding electromagnetic radiation  
25 reflected from the body part walls back towards to end of the illuminator, and a lens arranged to collimate the electromagnetic radiation from the convex reflector.

8. A probe as claimed in claim 7, in which the convex reflector is attached to the illuminator by a sheath substantially transparent to the electromagnetic radiation reflected from the walls of the anatomical.
- 5 9. A probe as claimed in claim 7 or claim 8, in which the convex reflector is a reflective ball.
10. A probe as claimed in claim 9, in which the ball is formed of stainless steel.
- 10 11. A probe as claimed in any one of the preceding claims, adapted to examine the walls of blood vessels.
12. A probe as claimed in claim 11, in combination with a catheter.
- 15 13. The combination as claimed in claim 12, in which the catheter is a balloon catheter for removing plaque formed on the blood vessel walls.
14. The combination as claimed in claim 13, in which the balloon catheter  
20 further comprises a cage around the balloon to assist in the removal of plaque.
15. A combination as claimed in claim 13 or claim 14, in which the probe is insertable into a 1 millimetre diameter balloon catheter, such that, in use, the blood vessel walls may be imaged and plaque may be removed therefrom  
25 substantially simultaneously.
16. A system for operating the probe of any one of claims 2 to 11, comprising generator means for generating electromagnetic radiation, the

illuminator being arranged to receive the electromagnetic radiation from the generator means; and display means for receiving the reflected electromagnetic radiation from the imaging means and displaying an image of the wall of the anatomical part.

5

17. A system as claimed in claim 16 when dependent upon claim 11, in which the generator means is arranged to generate electromagnetic radiation from the infrared portion of the electromagnetic spectrum.

10 18. A system as claimed in claim 17, further comprising a frequency shifter arranged to receive the reflected infrared electromagnetic radiation from the imaging means and shift the frequency thereof into the visible part of the electromagnetic spectrum prior to the radiation being received by the display means.

15

19. A probe constructed and arranged substantially as specifically described with reference to and as shown in Figures 1, 2a, 2b and 4 of the accompanying drawings.

20 20. A system constructed and arranged substantially as specifically described with reference to and as shown in Figure 3 of the accompanying drawings.

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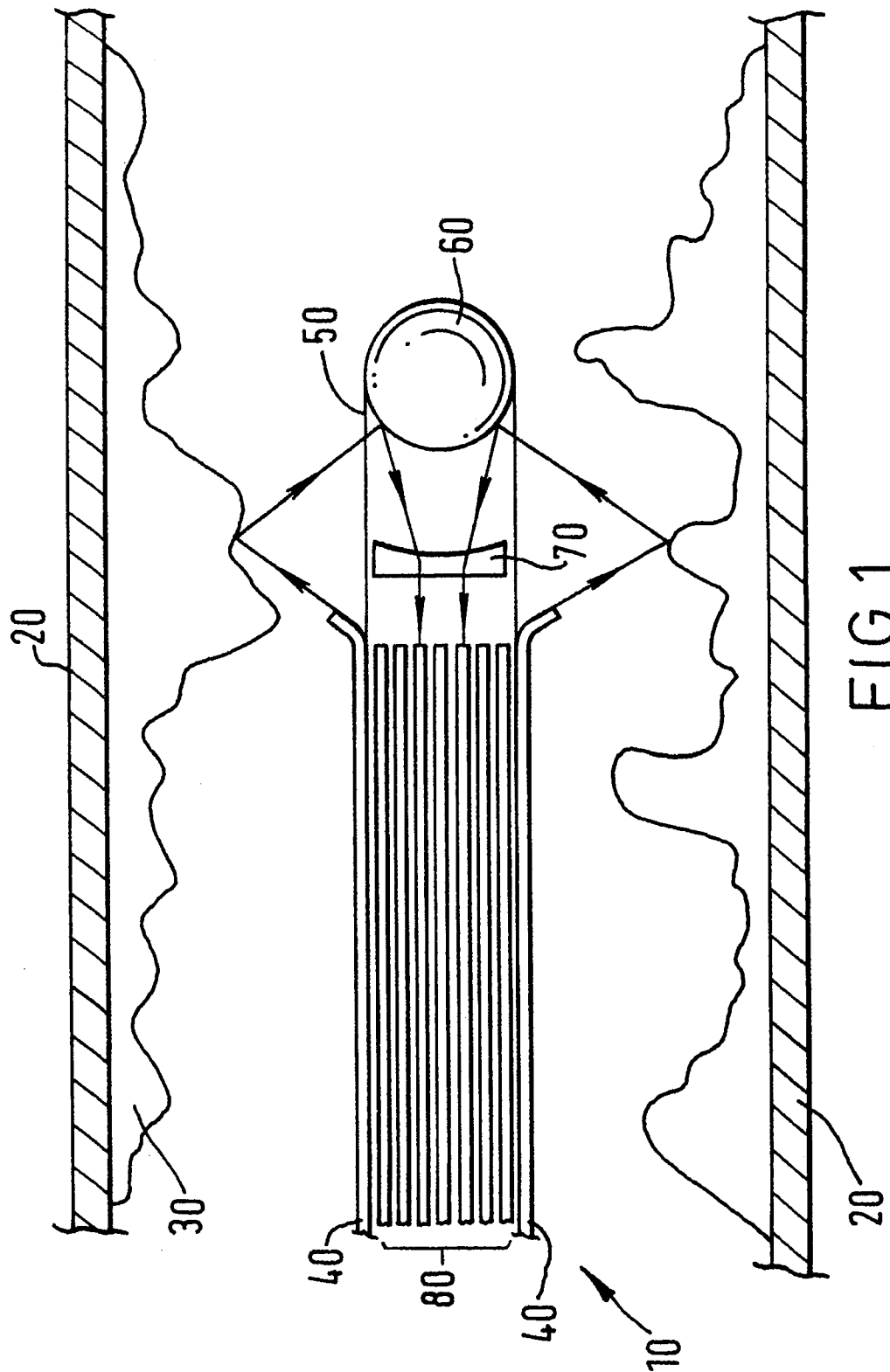


FIG. 1.



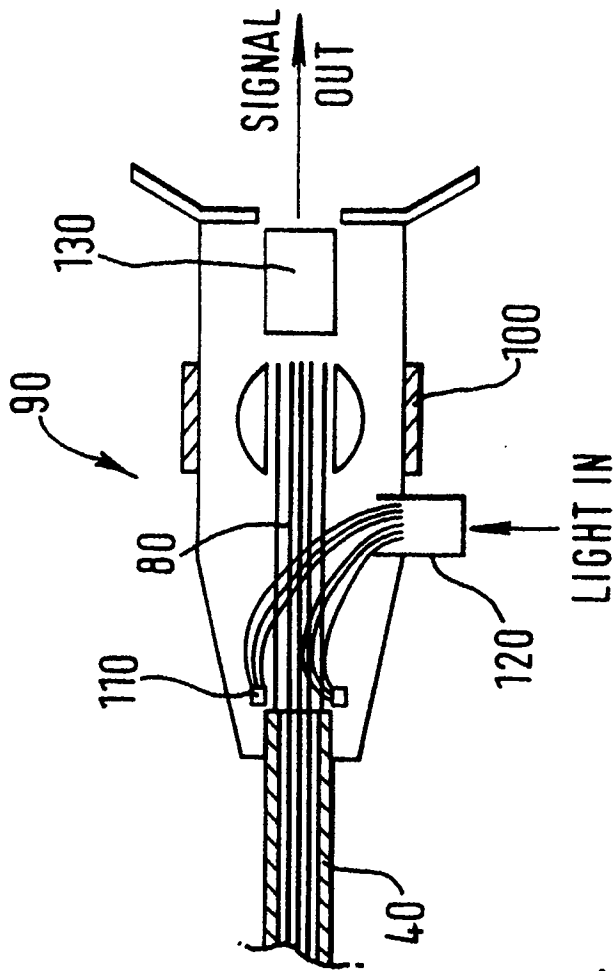


FIG. 2a.

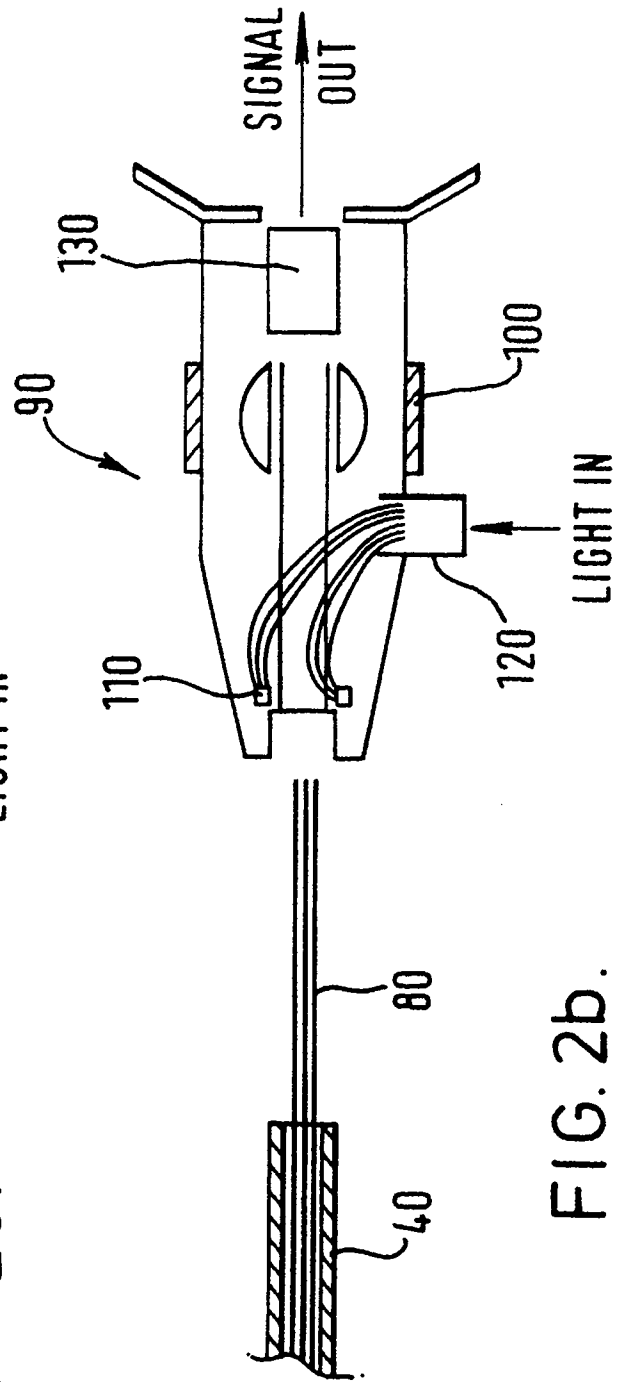


FIG. 2b.

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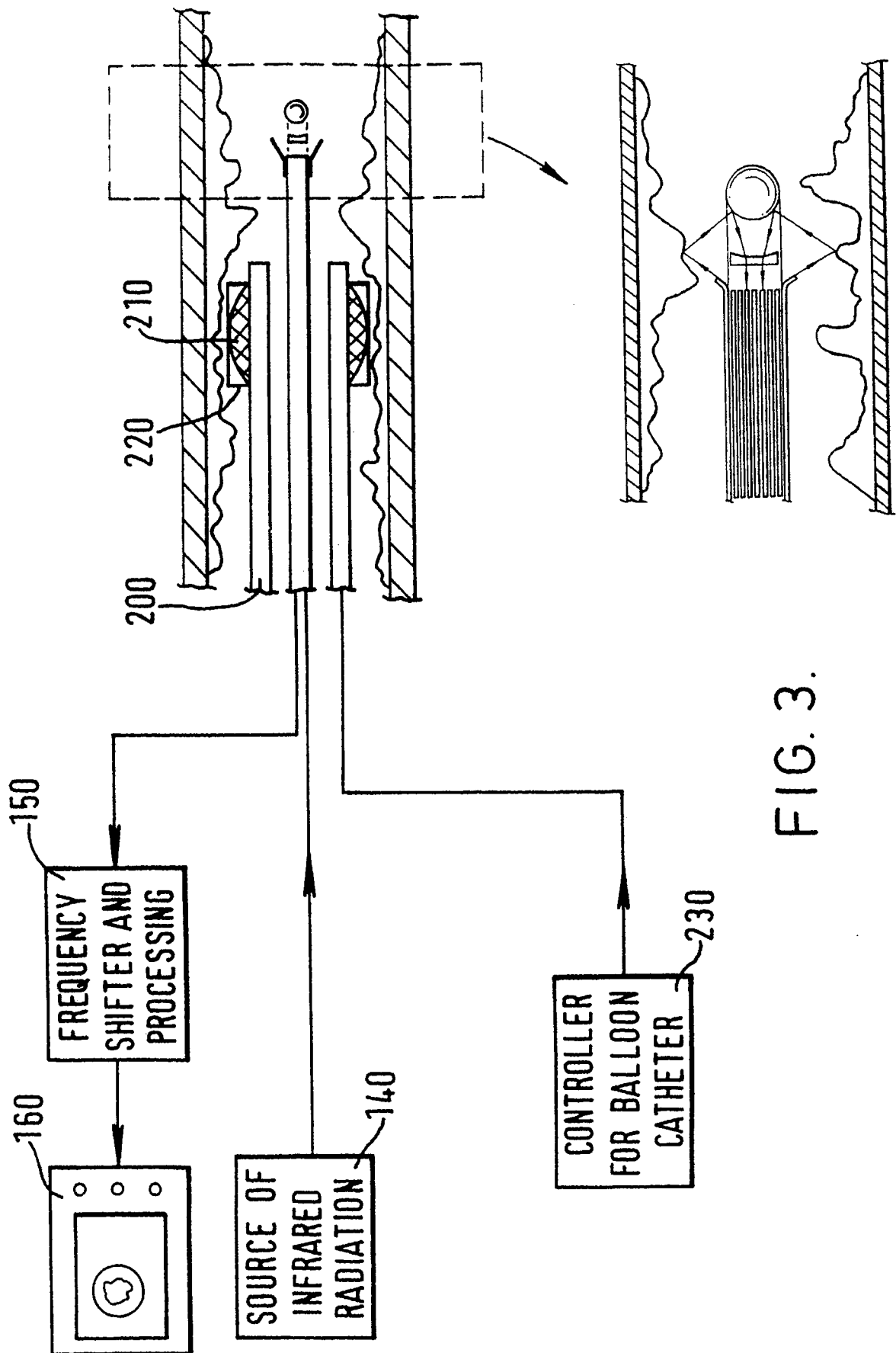


FIG. 3.

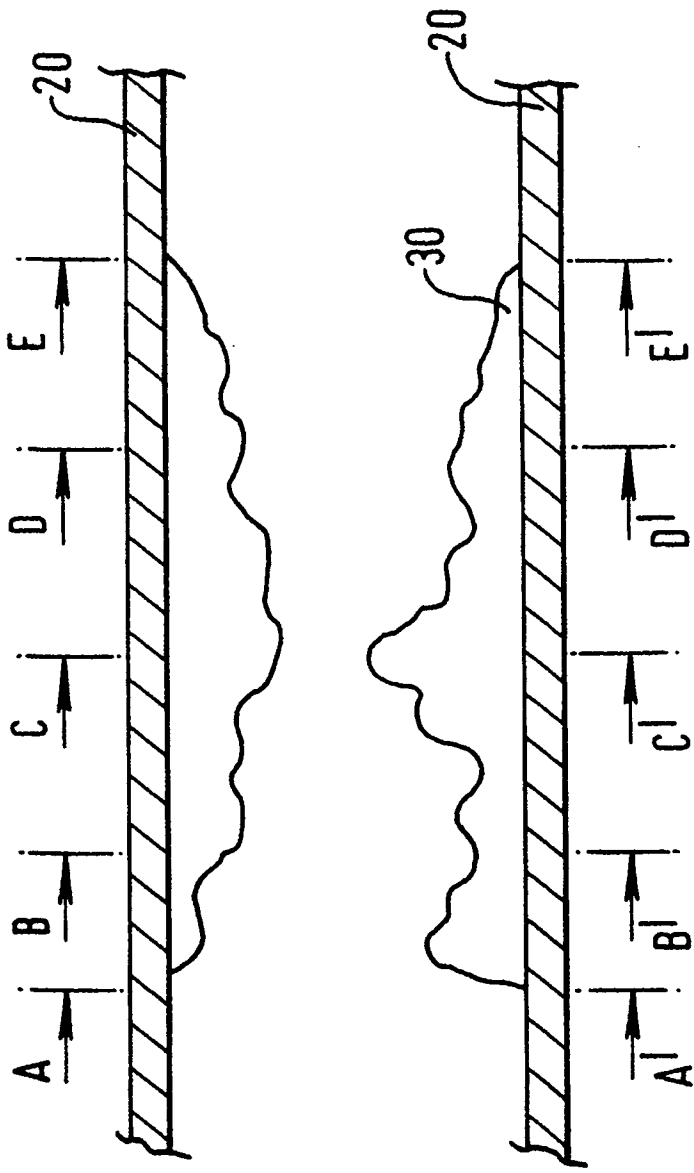


FIG. 4.

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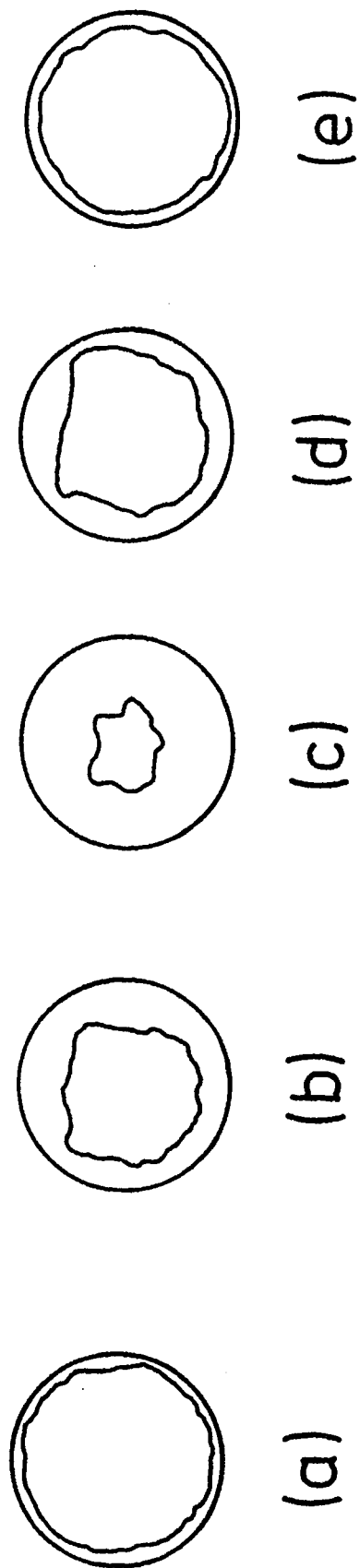


FIG. 5.

# INTERNATIONAL SEARCH REPORT

In tional Application No  
PCT/GB 98/01045

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 6 A61B5/00 A61B17/22

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	DE 92 17 571 U (BIOTRONIK) 27 January 1994  see page 1, line 3 - page 4, line 21 see page 6, line 6 - page 9, line 15 see page 10, line 26 - page 11, line 5; tables 1-3,5	1-6, 11-13,16 15
X A	US 5 411 016 A (KUME STEWART M ET AL) 2 May 1995 see column 4, line 46 - column 6, line 47 see column 7, line 39 - column 8, line 12; tables 1,2	1-6, 11-13,16 15
X A	WO 95 25460 A (SOC ET ET DE RECH BIOLOG ;SCHERNINSKI FRANCOIS (FR); QUENTEL GABRI) 28 September 1995 see page 7, line 19 - page 12, line 21; tables 1,2	1-6,16  17,18

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

8 July 1998

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Name and mailing address of the ISA

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# INTERNATIONAL SEARCH REPORT

Int. .ional Application No

PCT/GB 98/01045

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 467 459 A (EASTMAN KODAK CO) 22 January 1992	1-6,11
A	see abstract see column 3, line 40 - column 4, line 14 see column 7, line 6 - column 8, line 3; table 1 -----	17,18
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Information on patent family members

International Application No

PCT/GB 98/01045

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